DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 29, 2014

Iogyn, Inc.
Rich Christensen
Chief Operating Officer
20195 Stevens Creek Boulevard, Suite 120
Cupertino, CA 95014

Re: K141848
Trade/Device Name: Iogyn System
Regulation Number: 21 CFR§ 884.1710
Regulation Name: Closed Loop Hysteroscope Insufflator with Cutter-coagulator
Regulatory Class: II
Product Code: PGT
Dated: August 15, 2014
Received: August 18, 2014

Dear Rich Christensen,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

7.0 INDICATIONS FOR USE STATEMENT

Indications for Use Statement

510(k) Number	To be determined.
Device Name	**IOGYN System**
Indications For Use	The IOGYN System is intended to distend the uterus by filling it with saline to facilitate viewing with a hysteroscope during diagnostic and operative hysteroscopy and provide fluid management through the closed-loop recirculation of filtered distension fluid. It is also intended for cutting and coagulation of uterine tissue such as intrauterine polyps and myomas using a bipolar resecting device.

Prescription Use _X____ AND/OR Over-The-Counter Use_____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY

510(k) Summary for IOGYN System

A. Sponsor

IOGYN, Inc.

B. Contact

Rich Christensen
Chief Operating Officer
IOGYN, Inc
20195 Stevens Creek Blvd., Suite 120
Cupertino, CA 95014

Date Prepared: July 16, 2014

C. Device Name

Trade name:	IOGYN System
Common/usual Name:	Closed Loop Hysteroscopic Insufflator with Cutter-coagulator
Classification Name:	Closed Loop Hysteroscopic Insufflator with Cutter-coagulator

D. Predicate Device(s)

Trade name:	IOGYN System
Common/usual Name:	Closed Loop Hysteroscopic Insufflator with Cutter-coagulator
Classification Name:	Closed Loop Hysteroscopic Insufflator with Cutter-coagulator
Premarket Notification:	K132695

E. Device Description

Device Name: IOGYN System

The IOGYN System is comprised of the following:

- IOGYN Controller with Integrated Fluid Management
  - Footswitch
  - Fluid Management Accessories
- IOGYN Resecting Device

The IOGYN System provides an integrated control system with bipolar radiofrequency outputs (cut and coagulation) and fluid management through the use of two integrated peristaltic pumps. The Resecting Device is a bipolar radiofrequency device configured for the resection and aspiration of uterine pathology. Fluid infusion and aspiration of the uterine cavity are controlled by the IOGYN Controller's peristaltic pumps, in conjunction with the Fluid Management Accessories; these components form a closed-loop recirculating system. These integrated peristaltic pumps are operated by a software pressure control algorithm that measures and controls intra-uterine cavity pressure by varying saline infusion and aspiration rates in response to pressure changes during aspiration and tissue resection using the Resecting Device. The IOGYN Controller Graphical User Interface (GUI) has fluid control settings which allow the user to toggle infusion ON/OFF and to set the cavity pressure from 30-125mmHg.

The IOGYN System uses a closed-loop fluid management system with a single 3-liter saline bag that continuously recirculates filtered distension fluid throughout the procedure. The fluid absorption is limited by the volume within the 3-liter saline bag minus the dead volume within the system, which limits the deliverable volume to less than 2.5L. The 2.5L of recirculated fluid is passed through two levels of filtration - the first level of filtration removes resected tissue and bulk particles; the second level of filtration removes cellular materials, hemoglobin, plasma proteins, cytokines, coagulation factors, bacteria and viruses. These two levels of filtration generate optically clear, sterile, filtered distension fluid which is returned to the 3 liter saline bag and recirculated.

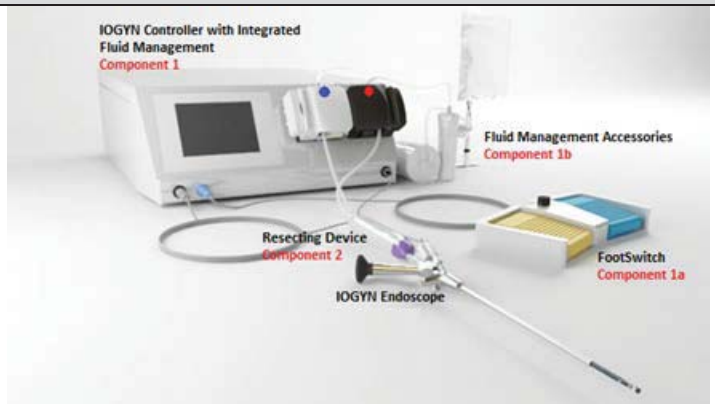
Components Description

The IOGYN System consists of the following components:

- Component 1: IOGYN controller with Integrated Fluid Management
- Component 1a: Footswitch
- Component 1b: Fluid Management Accessories
- Component 2: Resecting Device

The IOGYN System is for use with the IOGYN Endoscope. Refer to IOGYN Endoscope Instructions.

Figure 1: IOGYN System Components and IOGYN Endoscope

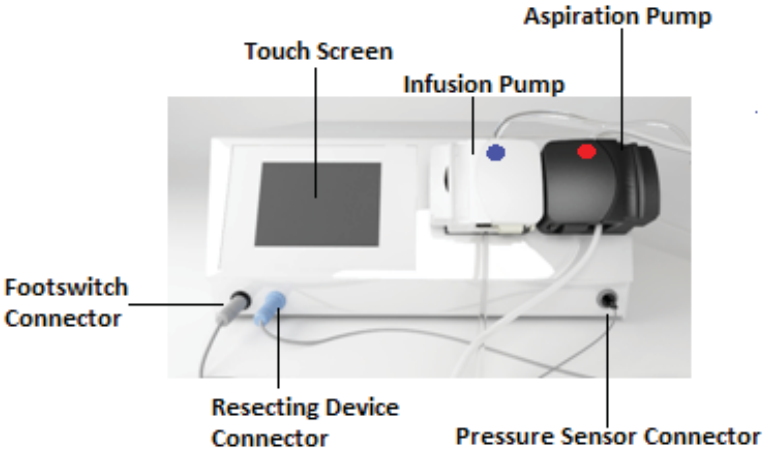


The IOGYN Controller includes:

- A touch screen with an intuitive Graphical User Interface (GUI) including user-adjustable cavity pressure control;
- RF cut and coagulation output for the IOGYN Resecting Device;
- Two pumps for the controlled infusion and aspiration of fluids and tissue;
- An electrical connection for pressure sensor monitoring of the uterine cavity pressure;

  A footswitch connection with the IOGYN Controller for user activation of RF energy and aspiration; and Accessories (footswitch, Fluid Management Accessories):

Figure 2: IOGYN Controller with Integrated Fluid Management

IOGYN Controller	Footswitch
	

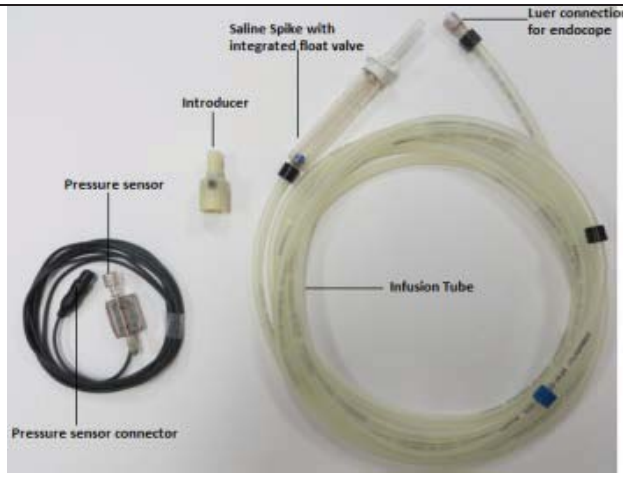
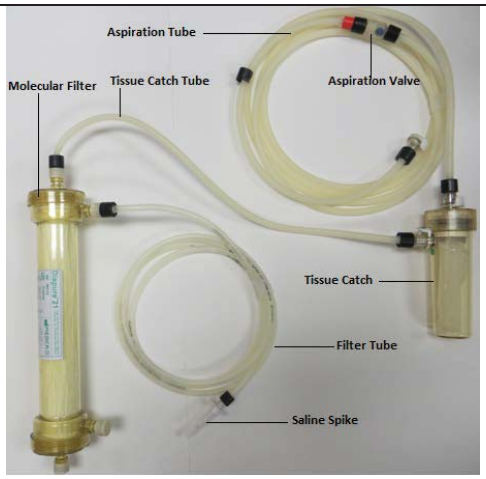
Component 1: The IOGYN Controller is provided non-sterile and is intended to be cleaned prior to use pursuant to provided instructions. (Figure 2).

Accessories to the IOGYN Controller consist of the (1) Footswitch and (2) the Fluid Management Accessories.

Component 1a: **The Footswitch** has a three button arrangement with individual pedals for cut, coagulation, and aspiration. (Figure 2). When acted upon by the user, it communicates with the IOGYN Controller to perform the designated function. The footswitch connects to the foot switch connector on the front of the IOGYN Controller.

Component 1b**: The Fluid Management Accessories** to the IOGYN Controller consist of infusion and aspiration tubing sets. (Figure 3). The infusion tubing set consists of a pressure sensor, an infusion tube and a disposable introducer seal for the endoscope. The infusion tube in conjunction with the infusion pump is responsible for insufflation of the uterine cavity via pressure feedback control from the pressure sensor to the IOGYN Controller. The aspiration tubing set consists of an aspiration tube, a container to collect tissue, a molecular filter and filter tubing. The aspiration tubing set in conjunction with the aspiration pump is responsible for the aspiration and filtration of uterine outflow and the subsequent recirculation into the 3-liter saline bag. The Fluid Management Accessories are provided sterile, as a single-use disposable device.

Figure 3: Fluid Management Accessories

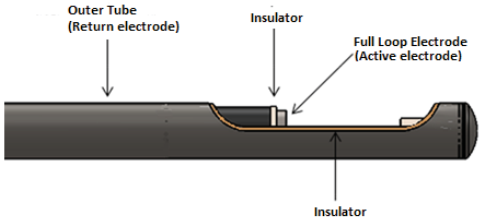
Fluid Management Accessories Infusion Tubing Set	**Fluid Management Accessories Aspiration Tubing Set**
	

Component 2: **The Resecting Device** is a sterile, single use disposable bipolar radiofrequency device for the resection and coagulation of tissue in a saline-insufflated environment. (Figure 4). The Resecting Device features an outer tube and an internal reciprocating electrode. The IOGYN Controller provides bipolar radiofrequency output to the Resecting Device sufficient for the cutting and

coagulation of tissue within the endoscopic environment. An internal full loop electrode reciprocates within the outer tube window, which is positioned at the distal tip of the device. When the RF Cut pedal is activated, the bipolar RF full-loop electrode moves distally to electro-surgically cut the tissue in the outer tube window. The resected tissue is simultaneously aspirated from the treatment site through the inner diameter of the full loop electrode, through the shaft and device handle area, and through the aspiration tube of the Fluid Management Accessories via the aspiration pump on the IOGYN Controller. When the RF Coagulation is activated, the bipolar RF full-loop electrode electro-surgically coagulates the tissue adjacent to the full loop electrode.

The Resecting Device is provided sterile, as a single-use disposable device.

Figure 4: Resecting Device

Resecting Device	Resecting Device Distal Tip
	

The device description for the modified device is identical to the device description of the Predicate Device cleared per K132695 with the exception of the following modifications:

1. Resecting Device:
    - The Inner Tube Electrical Insulation material is being changed from FEP (Fluorinated Ethylene Propylene) to Polyester. The material change is being made to improve manufacturing reliability by use of a material that is stiffer and shrinks at a lower minimum temperature than FEP.
    - The Outer Tube Electrical Insulation material is being changed from Aesno Med and Trogamid (Nylon/Polyamide) to Parylene C. The material change is being made to increase manufacturing reliability by reducing a multi-component assembly of two insulation materials to a single vapor deposited conformal coating.
2. Fluid Management Accessories:
    - The Infusion Tube material and dimensions are being changed from AdvantPure AdvantaFlex (OD: 5/16" ID: 3/16") to polyvinyl chloride (PVC) (OD: .355" ID: 1/4") and the Aspiration Tube material and dimensions are being changed from PureWeld XL Thermoplastic Elastomer (TPE) (OD: 5/16" ID: 3/16") to polyvinyl chloride (PVC) (OD: .355" ID: 1/4"). The PVC tubing also contains two colorants: Ultramarine

Blue and Ultramarine Violet. The material changes are being made to reduce supply chain risk associated with use of multiple vendors and to optimize cost structure.

F. Intended Use

The IOGYN System is intended to distend the uterus by filling it with saline to facilitate viewing with a hysteroscope during diagnostic and operative hysteroscopy and provide fluid management through the closed-loop recirculation of distention fluid. It is also intended for cutting and coagulation of uterine tissue such as intrauterine polyps and myomas using a bipolar resecting device.

G. Technological Characteristics

The proposed Resecting Device and the Fluid Management Accessories (components of the IOGYN System) have the same fundamental design, operating principles and the intended/indications for use as the predicate device (K132695). The proposed device has differences in materials and dimensions when compared to the cleared device (K132695).

H. Substantial Equivalence

The indications for use, technology and principles of operation of the IOGYN System remain unchanged when compared to the IOGYN System cleared per K132695. Modifications described above were confirmed to be acceptable by means of biocompatibility evaluation and appropriate bench/performance testing. The modified device is substantially equivalent to the predicate device.

I. Performance Testing (Bench Evaluation)

As a part of the design control and material change process, Fluid Management Accessories and Resecting Device test samples assembled with the material changes were subjected to extensive testing at the system, component, and subassembly levels to ensure that the material changes did not alter device, component or system performance and that the IOGYN System met its performance specifications. The following testing was complete to evaluate the effects of the design change:

- Biocompatibility testing per ISO 10993-1:2009 and FDA #G95-1
- Sterility testing per ANSI/AAMI/ISO 11137-2:2006(R)2010 and AAMI TIR33:2005.
- Shelf Life Testing ASTMF1980-07(2011)
- Transit Testing per ASTM D4169(2009)
- Performance Testing
  - Simulated Use
  - Durability Testing

- Hi Pot Testing
- Tensile Strength
- Flow Rate
- Pressure Testing
- System undeliverable volume (dead volume)

J. Conclusion

Biocompatibility test results were deemed acceptable for the intended use and the devices were considered biocompatible.

All device bench test results were acceptable. Data demonstrate that the Resecting Device and the Fluid Management Accessories meet design specifications and are suitable for the intended use and labeled shelf-life.

IOGYN, Inc. has demonstrated that the proposed modifications to the IOGYN System components are substantially equivalent to their predicate in IOGYN System (K132695).